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EXAMINER	
SINGH, SATYENDRA K	
ART UNIT	PAPER NUMBER
1657	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/566,445	BODINI ET AL.	
	Examiner	Art Unit	
	SATYENDRA K. SINGH	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25,26 and 28-48* is/are pending in the application.

4a) Of the above claim(s) *33-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25,26 and 28-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/28/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response and amendments to claims filed on 7/28/2009 is duly acknowledged.

Claims 25, 26 and 28-48 are pending in this application.

Claim 27 has been canceled by applicant's current amendment.

Claims 1-24 were canceled before, and claims 33-48 remain withdrawn.

Claims **25, 26 and 28-32** (corresponding to original group I, as amended) are examined on their merits in this office action.

NOTE: Applicants are advised that the dependence of newly presented **claim 42** (directed to an analysis kit) on instant claim 33 (the invention directed to a method of use) has been taken as a typographical error, and is presumed (in view of original claim 9 that depended from claim 1) to be depended from the product of group **I** (i.e. new claim 25 directed to the "induction solution"). Applicants are again advised to amend the claim 42 (although, currently withdrawn) appropriately to reflect this fact.

Claim Amendments

It is noted that applicants have amended **claim 29** to recite the limitation of "concentration of **about 0.5mM**" from "concentration of **about 0.05mM**" without following proper claim amendment guidelines (i.e. noncompliant claim amendments). In the interest of compact prosecution, however, the claim amendment has been taken as proper for the purposes of this office action as it corrects the concentration used in the example of the disclosure (see instant specification, page 12 and original claims). However, in future, applicants are advised to follow the proper procedural guidelines (i.e. 37 CFR 1.121(c)) while amending the claims under examination.

Claim Objections

1. Claim 28 is objected to because of the following informalities: claim 28 recites the limitation of **"alanina"** in line 2 that should be corrected to "alanine". Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 25, 26, and 29-32 (as amended) are rejected under 35 U.S.C. 102(b) as being anticipated by Chang et al (US 5, 411,867; [A]) as evidenced by Conda lab (TRYPTOSE, product brochure, catalog # 1614; [U]).

Claims are directed to **an induction solution** for rapid detection of coliforms, capable of inducing the expression of inducible enzymes beta-glucuronidase and beta-galactosidase, said solution comprising: a mixture of amino acids in such a quantity to not allow between 0 and 120 minutes, a detectable cell growth of coliforms in contact therewith; a buffer system; a bivalent ion; and an enzyme inducer consisting of isopropyl-beta-thiogalactopyranoside and/or methyl-beta-D-glucuronide, wherein said mixture of amino acids are at a concentration up to 80mM, and wherein said induction solution detects said coliforms in the absence of cell growth; wherein said bivalent ion is Mg++ and said Mg++ is used at a concentration of **about** 0.5 mM; wherein said isopropyl-beta-D-thiogalactopyranoside (IPTG) is used at a concentration of **about** 0.2 mM and/or said methyl-beta-D- glucuronide is used at a concentration of about 2 mM; and wherein said induction solution further comprises a selective agent that acts as a membrane permeabilizer such as sodium dodecyl sulphate (SDS). (see instant claims 26 and 29-32)

Chang et al [A] disclose an induction solution (suitable for rapid detection of coliforms, capable of inducing the expression of inducible enzymes beta-glucuronidase and beta-galactosidase; see abstract and summary, in particular), said solution comprising: a mixture of

amino acids (see example 3 at column 34 that uses tryptophan and tryptose, which is taken as a mixture of amino acids; see disclosed 18 out of 20 natural amino acids present in the "TRYPTOSE" product brochure from Conda lab, [U]); a buffer system (i.e. sodium-potassium phosphate buffer system); a bivalent ion such as magnesium sulfate; and an enzyme inducer such as IPTG, wherein said mixture of amino acids are at a concentration up to 80mM (i.e. ranging from **0 to 80 mM**; Chang et al use tryptophan at 5 mM, in addition to 1g/liter tryptose that supplies extra amino acids), and wherein said induction solution is capable of detecting said coliforms in the absence of cell growth (taken as an inherent feature of the disclosed composition); wherein said bivalent ion is Mg++ and said Mg++ is used at a concentration of 0.83 mM (taken as **about** 0.5 mM; the term "about" is not defined by applicants); wherein said isopropyl-beta-D-thiogalactopyranoside (IPTG) is used at a concentration of 0.42 mM (i.e. taken as **about** 0.2 mM; the term "about" is not defined by applicants); and wherein said induction solution further comprises a selective agent (that acts as a membrane permeabilizer) such as SDS (see example 3, in particular).

The limitations of claim 25 "wherein said induction solution detects said coliforms in the absence of cell growth" is taken as an inherent property of the induction solution as disclosed in the prior art reference of Chang et al, especially since it **comprises** all the components as recited in the instant claims of record (see recitation of claim 25, "said solution comprising").

As per MPEP 2111.01, *during examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names **joint inventors**. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 25, 26 and 28-32 (as currently amended) **are/remain** rejected under 35 U.S.C. 103(a) as being unpatentable over Nelis (US 5,861,270; issued on January 19, 1999; IDS) in view of Kuroda (PNAS, 1999; [U]).

Claims are directed to **an induction solution** for rapid detection of coliforms, capable of inducing the expression of inducible enzymes beta-glucuronidase and beta-galactosidase, said solution comprising: a mixture of amino acids in such a quantity to not allow between 0 and 120 minutes, a detectable cell growth of coliforms in contact therewith; a buffer system; a bivalent ion; and an enzyme inducer consisting of isopropyl-beta-thiogalactopyranoside and/or methyl-beta-D-glucuronide, wherein said mixture of amino acids are at a concentration **up to 80mM**, and wherein said induction solution detects said coliforms in the absence of cell growth (see

instant claims 26-28); wherein said bivalent ion is Mg++ and said Mg++ is used at a concentration of **about 0.5 mM**; wherein said isopropyl-beta-D-thiogalactopyranoside (IPTG) is used at a concentration of **about 0.2 mM** and/or said methyl-beta-D- glucuronide is used at a concentration of about 2 mM; and wherein said induction solution further comprises a selective agent such as sodium dodecyl sulphate (**SDS**).

Nelis (IDS) discloses an induction solution for rapid detection of coliform cells, capable of inducing the expression of inducible enzymes, beta-glucuronidase and beta-galactosidase, in the absence of growth of competing bacteria (see abstract, summary of the invention on column 2, column 4, and example 1 and 3, in particular), comprising: a protein hydrolysate such as tryptone and yeast extract, a buffer system such as monoammonium phosphate/dipotassium phosphate; a bivalent ion such as magnesium in the form of magnesium sulfate and magnesium chloride; and an enzymatic inducer consisting of IPTG; and wherein said induction solution further comprises a selective agent that acts as a membrane permeabilizer such as sodium dodecyl sulphate (SDS; see summary of the invention and columns 8, 1st paragraph, and column 9, example 3, in particular); and wherein beta-glucuronidase inducer such as methyl-beta-D-glucuronide may be used in said induction solution (see column 5, 1st paragraph and claim 20, in particular). Nelis discloses the problem with the growth of other non-coliform bacteria that produce background luminescence, and wants to reduce detection time and the quenching of light emission due to growth of non-target bacteria (see summary of the invention, and column 3, in particular).

However, an induction solution comprising **a mixture** of all 20 **amino acids** (claims 26-28; taken as isolated and purified amino acids supplemented to said solution) at a concentration of **about 80 mM** is not taught by the invention of Nelis.

Kuroda et al [U] disclose an induction solution (suitable for rapid detection of coliform cells, capable of inducing the expression of inducible enzymes, beta-glucuronidase and beta-

galactosidase, in the absence of cell growth) comprising at least one amino acid or a mixture of amino acids (see Kuroda et al, page 14264, "Materials and Methods", section on "Nutritional Downshift"; figure 3 and 6, in particular), wherein said amino acid concentration is at about 10 micromolar to about 0.4 mM (uses supplementation of **all 20 natural amino acids** at 1.25, 10, and 50 mg/liter; see figure 6 and its legend, page 14267, left column, in particular); a buffer system such as MOPS, pH 7.2; a bivalent ion such as magnesium or calcium; and an enzymatic inducer consisting of isopropyl-beta-D-thiogalactopyranoside (IPTG) at a concentration of 1 mM (see legend of figure 6 A and B). In addition, Kuroda et al demonstrates induction of beta-galactosidase (i.e. lacZ expression) by the nutritional downshift in the wild type *E. coli* (see page 14266, right column, last paragraph, in particular), and the fact that availability of free amino acids (supplemented in the MOPS minimal growth medium) is important for the enzyme production (i.e. beta-galactosidase) after the nutritional down shift (see page 14267, right column, 1st paragraph, in particular).

Thus, at the time the claimed invention was made, it would have been obvious to an artisan of ordinary skill in the microbial detection art to modify the induction solution of Nelis (see discussion above) such that it uses a defined medium supplemented with purified amino acid(s) or a combination thereof (as taught by Kuroda et al; instead of protein hydrolysates such as yeast extract and peptone; see Kuroda et al page 14264, section "nutritional downshift", in particular) in order to avoid high background due to non-coliform bacterial growth and thus higher background fluorescence resulting from growth on rich medium.

Since, Kuroda et al disclose the benefits of nutritional downshift in terms of the induction of beta-galactosidase by amino acid supplementation, one of the marker enzymes used in

detection of coliforms by Nelis, one of ordinary skill in the art would have been motivated at the time of invention to make this modification/substitution in the induction solution of Nelis in order to obtain a better and sensitive induction solution as suggested by the combined teachings of the cited prior art references, with a reasonable expectation of success.

The limitations of molar concentrations of amino acids (that allows no detectable coliform cell growth within a time period of between 0-120 minutes), magnesium ions, and enzymatic inducers used in the induction solution would have been obvious to an artisan of ordinary skill in the microbial detection art at the time this invention was made because the cited prior art references of Nelis and Kuroda et al disclose various combinations of concentrations (see for amino acids supplementation of a defined medium, Kuroda et al, figure 6, legend, in particular; and for both Nelis and Kuroda et al for the amounts of bivalent ion such as magnesium, IPTG, etc.; see discussion above) that may be further varied by an artisan of ordinary skill depending upon the specific requirement of the detection system, and in order to obtain a highly sensitive assay for coliforms having lower background fluorescence, as desired by the disclosure of Nelis (see discussion of Nelis above). Since, the nutritional downshift is known to reduce growth of bacteria on a defined medium as explicitly disclosed by Kuroda et al, the use of amino acid supplementation to help induce lacZ expression (with the help of an enzymatic inducer such as IPTG) as an enzymatic marker in a rapid detection system for coliforms would have been obvious to an artisan at the time the claimed invention was made. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references.

Thus, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill in the art at the time the claimed invention was made.

As per MPEP 2111.01, *during examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

As per MPEP 2144.06, *In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. In re Ruff, 256 F.2d 590, 118 USPQ 340 (CCPA 1958).*

As per MPEP 2144.05 [R3], II. OPTIMIZATION OF RANGES - A. Optimization Within Prior Art Conditions or Through Routine Experimentation: *Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).*

Response to Arguments

Applicant's arguments filed 07/28/2009 (as they pertain to the prior art rejection of record) have been fully considered but they are not persuasive for the following reasons of record:

Applicants argue the following (see remarks, page 7):

> "..As set forth in more detail in the specification, tryptophan, leucine and isoleucine were important ingredients, while the simultaneous absence of methionine and threonine strongly reduced the inducing effect. As noted in the specification, in general, a proportioned combination of amino acids gave good results. All other components are present in a minimal amount only to allow survival of the cells and expression of the enzyme activity. Indeed, Applicants discovered that microbial growth is strongly prevented, due to the scarcity of ingredients contained in the original "induction solution". Applicants respectfully submit that this is the first time that a no-growth medium, presenting a fully and clearly defined composition, is employed to face the problem of detecting a very limited amount of coliforms/E, coli and like bacteria in a sample in such a short time. Applicants discovered that the selectivity of the claimed action is actually guaranteed from the induction of specific enzymes".

It is noted that instant claims are directed to an "induction solution" (i.e. a product composition comprising certain types of components; see claim 25, in particular) for rapid

detection of coliforms, wherein said solution is capable of inducing the expression of inducible enzymes such as beta-galactosidase and beta-glucuronidase, and wherein the solution comprises a buffer system, a bivalent ion, an enzyme inducer and a mixture of amino acids at a concentration up to 80 mM. A composition as currently claimed has been fully disclosed in the prior art (see 102b rejection of record on the claims as currently amended) as discussed above.

As per the obviousness rejection of record over Nelis in view of Kuroda et al, applicant's arguments that "(A)s noted in the specification, in general, *a proportioned combination of amino acids* gave good results", and "..that this is the first time that a *no-growth medium*, presenting a fully and clearly defined composition, is employed to face the problem of detecting a very limited amount of coliforms/E, coli and like bacteria in a sample in such a short time", is fully considered but is not found to be persuasive because claims as currently presented do not recited "*a proportioned combination of amino acids*", rather a mixture of amino acids that can be at a concentration **up to 80 mM**. In addition, an induction solution "comprising" a mixture of amino acids at a concentration "up to 80 mM" will not necessarily be characterized as a "*no growth medium*" by an artisan of ordinary skill in the biochemical and microbial art at the time this invention was made. Moreover, as pointed out in the 103(a) rejection above, Nelis is aware of the fact and wants to reduce the growth (and therefore background fluorescence; see column 3, 1st paragraph, and lines 35-39, in particular) of other non-coliform bacteria, the growth of which may contribute to higher background, and thus lower sensitivity of detection of coliforms. The argument (see remarks, page 8) that "..(A)pplicant aims to an enzyme induction in the absence of cell proliferation, as claimed. Whereas Nelis and like references detect coliforms and such by virtue of their growth or cell proliferation, the present invention does not rely on cell growth and

operates quite differently" is fully noted. However, it is not found to be persuasive because the composition and its components as currently claimed are fully disclosed in the prior art, and the substitution of tryptone or yeast extract used by Nelis with a mixture of all 20 natural amino acids (in view of the disclosures from Kuroda et al) such that it provides a poor growth medium, better suited for reducing background fluorescence, and enhancing the sensitivity of detection of coliforms, would have been obvious and fully contemplated by an artisan of ordinary skill in light of the combined teachings of the cited prior art references of record.

Applicants further argue the following (see remarks, page 8):

> "However, Applicants respectfully submit that there is an extremely important point that must be noted here: the whole of Kuroda's investigation concerns nutritional downshifts from rich 2 x YT medium to minimal MOPS medium. This means that the above mentioned induction of lacZ is described only in conditions of amino acids supplemented to the MOPS minimal growth medium. Additionally, it is clearly indicated that the amino acids also cause remarkable reduction of growth lag and thus they are added in Kuroda in order to support cell growth recovery. This is in complete contrast with the induction solution claimed herein by the Applicants, which targets the use of amino acids for the expression of inducible enzymes in the absence of cell growth"

Applicant's argument (regarding growth in MOPS-minimal medium used by Kuroda et al) are not found to be persuasive because Kuroda et al clearly suggest the fact that supplementation of amino acids at low concentrations to the minimal medium enabled expression of the inducible enzyme such as beta-galactosidase (see Kuroda et al, page 14264, left column, and figure 6, in particular), and that availability of amino acids is important for enzyme production after the nutritional downshift, which will occur during the process of detection when the coliforms containing samples are contacted with said "induction solution" comprising mixture of amino acids. Moreover, given the recitation in claim 25 "in such a quantity to not allow, **between 0 and 120 minutes**, a detectable cell growth of coliforms in contact therewith",

it is clear that no coliform growth will be anticipated at "0" time point. It is also to be pointed out that depending on the concentration of the amino acid mixture used in the induction solution, one would expect cell growth over a period of time, especially at higher mM concentrations of amino acids in said induction solution, as currently claimed. In addition, the argument (see remarks, page 9) that "*..(T)he use of amino acids in the absence of other nutritional components is not contemplated, not disclosed and not suggested*", is noted but is not found to be persuasive because claim 25 as recited (i.e. the comprising language), is not limited to just the mixture of amino acids as currently argued by applicants, and is open to further additions. Further more, the table on page 9-10 showing the applicant's perceived differences in terms of sources of carbon, nitrogen, amino acids, minerals, etc. used by Nelis, Kuroda et al and the instant invention, is noted. However, the components as recited in claim 25 are fully disclosed in the art, and therefore, the applicant's arguments based on functional limitations are not found to be persuasive. On the other hand amino acids can act as a source of nitrogen, or carbon, etc. depending on the availability of nutrients and other conditions that are encountered by a bacterial cell.

Applicant's characterization of MOPS-minimal medium (based on Neidhardt et al; see remarks, page 10-12, in particular) and its use in supporting bacterial growth under certain conditions is duly acknowledged. However, the **scope of the showing must be commensurate with the scope of claims** to consider evidence probative of unexpected results, for example. *In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980).* It should be clear

from the record that the probative value of the showing is not commensurate in scope with the degree of protection sought by the instant claims (see instant claim 25, in particular). The arguments that "*..the induction solution of the present invention, as claimed, forces bacteria to allow only one pathway, the production of the requested enzyme, whereas the MOPS supplemented with amino acids and the "improved luminescence medium" support favourable conditions for duplication and expression of different metabolic pathways, as set forth in Nelis, Kuroda and any combinations thereof*" is noted but is not found to be persuasive because applicants have not disclosed the fact that higher concentrations of amino acids in the induction solution as claimed (for example, 80 mM total concentration of amino acids) will not result in growth within 120 minutes, as currently being argued. In fact, the example 1 (see instant specification, page 12, paragraph [0035], in particular) as disclosed by applicants only uses about 0.3 mM of total concentration of a mixture of all 20 natural amino acids (i.e. 4 micrograms each, a total of 80 micrograms in 2315 microliter), and no other disclosure is provided in order to show that a concentration (of the mixture of amino acids) up to 80 mM will necessarily result in the same functional property (i.e. no growth within 2 hours during presumed detection process) as currently being argued by applicants. The obviousness rejection of record is therefore properly made & maintained.

Applicant's argument (see remarks, page 13) that "(T)he references cited by the Examiner but not applied appear of no more relevance than the art cited" is not found to be persuasive because Chang et al has been now relied upon as a 102b prior art (see new rejection above, after removal of new matter) as necessitated by applicant's current claim amendments.

Conclusion

NO claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SATYENDRA K. SINGH whose telephone number is (571)272-8790. The examiner can normally be reached on 9-5MF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Satyendra K. Singh/
Examiner, Art Unit 1657

/Irene Marx/
Primary Examiner
Art Unit 1651